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**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| MUTUAL PHARMACEUTICAL COMPANY, INC., et al.,<br><br>Plaintiffs,<br><br>v.<br><br>WATSON PHARMACEUTICALS, INC., et al.,<br><br>Defendants. | Civil Action No. 09-5421(GEB)(TJB)<br><br>**PLAINTIFFS' SUPPLEMENTAL STATEMENT OF DISPUTED MATERIAL FACTS** |

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Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc. (collectively, "Plaintiffs"), pursuant to Local Civil Rule 56.1(a), respectfully submit their Supplemental Statement of Disputed Material Facts ("Supplemental Statement") in Support of their to Opposition to the Motion for Summary Judgment Filed by Defendant West-Ward Pharmaceutical Corp. ("Defendant" or "West-Ward"). Plaintiffs submit this Supplemental Statement, along with their Opposition to the Motion for Summary Judgment and Responsive Statement of Material Facts, in support of their request that this Court deny Defendant's Motion for Summary Judgment based on its assertion of an unclean hands defense.

## SUPPLEMENTAL STATEMENT OF DISPUTED MATERIAL FACTS

1. From 1993 to 2006, Mutual sold unapproved colchicine during a time period when no manufacturer had received FDA approval for single ingredient colchicine. Furthermore, the new safety information generated as a result of Mutual going through the FDA-approval process for its COLCRYS® colchicine product had not yet been discovered. Declaration of G. Hayer ("Hayer Decl.) at ¶¶5, 18-19.

2. In June 2006, the FDA announced a new drug safety initiative to remove unapproved drugs from the market. *Id*. at ¶3; *see also* Exhibits A, F, and G to the Declaration of N. Kottahachchi ("Kottahachchi Decl.").

3. In response to the FDA's guidance stating that drug manufacturers either seek FDA approval of unapproved drugs or remove them from the market, Plaintiffs ceased production of all unapproved drugs and also began the process of seeking FDA approval for certain drugs, including colchicine. Hayer Decl. at ¶¶4, 9; *see also* Exhibit I to the Kottahachchi Decl. at Response No. 16.

4. Plaintiffs have not shipped or sold any unapproved colchicine products since July 2006. Hayer Decl. at ¶7; *see also* Exhibit I to the Kottahachchi Decl. at Response No. 16.

5. During the time that Mutual sold unapproved colchicine, there was no FDA-approved single ingredient colchicine product available on the market. There was no FDA-approved single ingredient colchicine product available until Mutual obtained FDA-approval for its COLCRYS® product. Hayer Decl. at ¶5.

6. [redacted]

7. Plaintiffs expended significant resources in pursuing FDA approval for their colchicine product, which included significant time and money spent on clinical trials, data assessment, and the submission process to the FDA. Hayer Decl. at ¶9.

8. Plaintiffs' testing and clinical trials conducted during the FDA approval process for COLCRYS® demonstrated that colchicine has potentially serious adverse health risks if the drug is not administered in proper dosage and if colchicine is administered in interaction with other identified drugs and foods. These findings resulting in specific safety improvements in administering colchicine, which included: (a) the development of new dosing regimens for COLCRYS® aimed at reducing the total amount of colchicine used by patients, which in turn significantly decreased the most common side effects from colchicine use (*i.e.*, adverse effects involving the gastrointestinal tract, including cramping, nausea, diarrhea, abdominal pain and vomiting); (b) the discovery of potentially serious drug-drug and food interactions between colchicine and certain other foods and drugs, as well as specific dosing regimens that help ameliorate potential negative interactions; and (c) the development of the more accurate and safer labeling of COLCRYS®, which now lists and warns of numerous drug-drug interactions, food interactions, contraindications, and the potentially dangerous accumulation of colchicine during chronic dosing. *Id*. at ¶18;.

9. The new safety information resulting from Plaintiffs' clinical trials during the FDA approval process was not known at the time Plaintiffs distributed unapproved colchicine prior to 2006. Hayer Decl. at ¶19.

10. Plaintiffs' product inserts and labels of COLCRYS® incorporated information about the new safety data. *Id*. at ¶18. The FDA also required Plaintiffs to include a Medication Guide with COLCRYS®, which includes important warnings about various drug-drug and food interactions. *Id*. at ¶20.

11. Plaintiffs' COLCRYS® product inserts and labels incorporate the newly discovered safety information and are, thus, significantly different and safer than any products inserts and labels utilized by Defendant West-Ward and the other defendants for their unapproved colchicine products. *Id*. at ¶18; Exhibit H to the Kottahachchi Decl., at Response No. 17.

12. Defendant is aware of the health risks of unapproved colchicine, yet their product inserts and labels have not changed to incorporate the newly discovered safety information. Exhibit H to the Kottahachchi Decl., at Responses Nos., 2-7, 17. Nor has West-Ward taken any steps to have its unapproved colchicine products removed from the Price Lists and Wholesale Ordering Systems. Exhibit H to the Kottahachchi Decl., Responses Nos. 14-15.

13. Plaintiffs did not distribute unapproved colchicine at any time when an FDA-approved single ingredient colchicine product was on the market, like

Defendant West-Ward and the other defendants do now. Hayer Decl. at ¶5; Exhibit H to the Kottahachchi Decl., Responses Nos. 2-7. Plaintiffs did not distribute unapproved colchicine with outdated health risk information and safer prescribing protocols available, like Defendant West-Ward and the other defendants do now. Hayer Decl. at ¶19; Exhibit H to the Kottahachchi Decl., at Response No. 17.

14. The FDA has issued warning letters to three manufacturers of unapproved colchicine and in all three letters the FDA states that colchicine requires FDA approval to be legally marketed in the United States. *See* Exhibits B-D to the Kottahachchi Decl., FDA warning letters to Sunrise Pharmaceutical, Inc., Concord Laboratories, Inc., and Defendant Vision Pharma LLC.

15. [redacted]

16. The FDA has in no way approved or condoned the continued sale of unapproved colchicine by Defendant West-Ward or any of the other defendants. Exhibits A, D, and G to the Kottahachchi Decl. In addition, the FDA's website makes clear that "The inclusion of a firm or its products in the NDC Directory does not denote approval by the FDA of the firm or any of its marketed products." Exhibit E to the Kottahachchi Decl.

17. [redacted]

Dated: August 23, 2010

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